

PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1 Sheets

Substitute for form 1449A/PTO		<i>Complete If Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		Application Number	10/619,939
		Filing Date	07/15/2003
		First Named Inventor	Ruxandra Draghia-Akli, et al.
		Group Art Unit	1636
		Examiner Name	D. Sullivan
		Attorney Docket Number	AVSI-0023 (108328.00146)
Sheet	1	of	1 Sheets

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)			
					T <sup>6</sup>

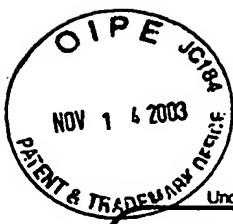
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<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 1 of 6 Sheets

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	10/619,939
(use as many sheets as necessary)		Filing Date	7/15/2003
		First Named Inventor	Draghia-Akli, Ruxandra
		Group Art Unit	1636
		Examiner Name	D. Sullivan
Sheet	1	of	6 Sheets
		Attorney Docket Number	108328.00146 (AVSI-0023)

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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of

6 Sheets

*Complete If Known*

Application Number	10/619,939
Filing Date	7/15/2003
First Named Inventor	Draghia-Akli, Ruxandra
Group Art Unit	1636
Examiner Name	D. Sullivan

Attorney Docket Number 108328.00146 (AVSI-0023)

### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
DS	6	AIHARA, H. and Miyazaki, J. (1998). Gene transfer into muscle by electroporation in vivo. Nat. Biotechnol. 16, 867-870.	
	7	BAIRD, A., Wehrenberg, W. B., and Ling, N. (1986). Relative potencies of human, rat, bovine/caprine, porcine and ovine hypothalamic growth hormone-releasing factors to release growth hormone by the rat anterior pituitary in vitro. Neuroendocrinology 42, 273-276.	
	8	BERCU, B. B., Walker, R. F., (1997). Growth Hormone Secretagogues in Children With Altered Growth. Acta Paediatrica 86, 102-106.	
	9	BLETHEN, S. L. (1995). Complications of growth hormone therapy in children. Curr. Opin. Pediatr. 7, 466-471.	
	10	BLETHEN, S. L. and Rundle, A.C. (1996). Slipped capital femoral epiphysis in children treated with growth hormone. A summary of the National Cooperative Growth Study experience. Horm. Res. 46, 113-116.	
	11	BOHLEN, P., Esch, F., Brazeau, P., Ling, N., and Guillemin, R. (1983). Isolation and characterization of the porcine hypothalamic growth hormone releasing factor. Biochem. Biophys. Res. Commun. 116, 726-734.	
	12	BOHLEN, P., Wehrenberg, W. B., Esch, F., Ling, N., Brazeau, P., and Guillemin, R. (1984). Rat hypothalamic growth hormone-releasing factor: isolation, sequence analysis and total synthesis. Biochemical & Biophysical Research Communications 125, 1005-1012.	
	13	BRAZEAU, P., Bohlen, P., Esch, F., Ling, N., Wehrenberg, W. B., and Guillemin, R. (1984). Growth hormone-releasing factor from ovine and caprine hypothalamus: isolation, sequence analysis and total synthesis. Biochemical & Biophysical Research Communications 125, 606-614.	
DS	14	BURGERT, T. S., Vuguin, P. M., DiMartino-Nardi, J., Attie, K. M., and Saenger, P. (2002). Assessing insulin resistance: application of a fasting glucose to insulin ratio in growth hormone-treated children. Horm. Res. 57, 37-42.	

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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Sheet 3 of 6 Sheets

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Application Number	10/619,939
Filing Date	7/15/2003
First Named Inventor	Draghia-Akli, Ruxandra
Group Art Unit	1636
Examiner Name	D. Sullivan

Attorney Docket Number 108328.00146 (AVSI-0023)

## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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DS	15	CARREL, A. L. and Allen, D. B. (2000). Effects of growth hormone on body composition and bone metabolism. Endocrine. 12, 163-172.	
/	16	CORPAS, E., Harman, S. M., and Blackman, M. R. (1993a). Human growth hormone and human aging. [Review]. Endocrine Reviews 14, 20-39.	
/	17	CORPAS, E., Harman, S. M., Pineyro, M. A., Roberson, R., and Blackman, M. R. (1993b). Continuous subcutaneous infusions of growth hormone (GH) releasing hormone 1-44 for 14 days increase GH and insulin-like growth factor-I levels in old men. Journal of Clinical Endocrinology & Metabolism 76, 134-138.	
/	18	CUTTLER, L. (1996). The regulation of growth hormone secretion. Endocrinol. Metab Clin. North Am. 25, 541-571.	
/	19	DANKO, I. and Wolff, J. A. (1994). Direct gene transfer into muscle. [Review]. Vaccine 12, 1499-1502.	
/	20	DARQUET, A. M., Cameron, B., Wils, P., Scherman, D., and Crouzet, J. (1997). A new DNA vehicle for nonviral gene delivery: supercoiled minicircle. Gene Ther. 4, 1341-1349.	
/	21	DARQUET, A. M., Rangara, R., Kreiss, P., Schwartz, B., Naimi, S., Delaere, P., Crouzet, J., and Scherman, D. (1999). Minicircle: an improved DNA molecule for in vitro and in vivo gene transfer. Gene Ther. 6, 209-218.	
/	22	DRAGHIA-AKLI, R., Fiorotto, M. L., Hill, L. A., Malone, P. B., Deaver, D. R., and Schwartz, R. J. (1999). Myogenic expression of an injectable protease-resistant growth hormone-releasing hormone augments long-term growth in pigs. Nat. Biotechnol. 17, 1179-1183.	
/	23	DRAGHIA-AKLI, R., Li, X. G., Schwartz, R. J. (1997). Enhanced Growth By Ectopic Expression Of Growth Hormone Releasing Hormone Using An Injectable Myogenic Vector. nature biotechnology 15, 1285-1289.	
DS	24	DRAGHIA-AKLI, R., Malone, P. B., Hill, L. A., Ellis, K. M., Schwartz, R. J., and Nordstrom, J. L. (2002). Enhanced animal growth via ligand-regulated GHRH myogenic-injectables vectors. FASEB J. 16, 426-428.	

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				Group Art Unit	1636
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<b>OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS</b>				
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DS	25	DUCK, S. C., et al., (1992). Subcutaneous growth hormone-releasing hormone therapy in growth hormone-deficient children: first year of therapy. <i>Journal of Clinical Endocrinology &amp; Metabolism</i> 75, 1115-1120.		
	26	ESCH, F., Bohlen, P., Ling, N., Brazeau, P., and Guillemin, R. (1983). Isolation and characterization of the bovine hypothalamic growth hormone releasing factor. <i>Biochemical &amp; Biophysical Research Communications</i> 117, 772-779.		
	27	EVANS, W. S., Vance, M. L. et al., (1985). Effects of intravenous, subcutaneous, and intranasal administration of growth hormone (GH)-releasing hormone-40 on serum GH concentrations in normal men. <i>Journal of Clinical Endocrinology &amp; Metabolism</i> 61, 846-850.		
	28	FAGLIA, G., Arosio, M., and Bazzoni, N. (1992). Ectopic acromegaly. [Review]. <i>Endocrinology &amp; Metabolism Clinics of North America</i> 21, 575-595.		
	29	FROHMAN, L. A., Downs, T. R., and Chomczynski, P. (1992). Regulation of growth hormone secretion. [Review]. <i>Frontiers in Neuroendocrinology</i> 13, 344-405.		
	30	FROHMAN, L. A., Downs, T. R., Heimer, E. P., and Felix, A. M. (1989a). Dipeptidylpeptidase IV and trypsin-like enzymatic degradation of human growth hormone-releasing hormone in plasma. <i>J. Clin. Invest.</i> 83, 1533-1540.		
	31	FROHMAN, L. A., Downs, T. R., Williams, T. C., Heimer, E.P., Pan, Y.C., and Felix, A.M. (1986). Rapid enzymatic degradation of growth hormone-releasing hormone by plasma in vitro and in vivo to a biologically inactive product cleaved at the NH <sub>2</sub> terminus. <i>J. Clin. Invest.</i> 78, 906-913.		
	32	GEFFNER, M. (1997). Effects of growth hormone and insulin-like growth factor I. <i>Acta Paediatr. Suppl</i> 423, 76-79.		
DS	33	HART, D. W., Herndon, D. N., Klein, G., Lee, S. B., Celis, M., Mohan, S., Chinkes, D. L., and Wolf, S. E. (2001). Attenuation of posttraumatic muscle catabolism and osteopenia by long-term growth hormone therapy. <i>Ann. Surg.</i> 233, 827-834.		

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5 of 6 Sheets

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DS	34	KOTZMANN, H., Yilmaz, N., Lercher, P., Riedl, M., Schmidt, A., Schuster, E., Kreuzer, S., Geyer, G., Frisch, H., Horl, W. H., Mayer, G., and Luger, A. (2001). Differential effects of growth hormone therapy in malnourished hemodialysis patients. Kidney Int 60, 1578-1585.	
	35	LAL, S. O., Wolf, S. E., and Herndon, D. N. (2000). Growth hormone, burns and tissue healing. Growth Horm. IGF. Res. 10 Suppl B:S39-43., S39-S43.	
	36	LEROITH, D., Yanowski, J., Kaldjian, E. P., Jaffe, E. S., LeRoith, T., Purdue, K., Cooper, B. D., Pyle, R., and Adler, W. (1996). The effects of growth hormone and insulin-like growth factor I on the immune system of aged female monkeys. Endocrinology 137, 1071-1079.	
	37	LESBORDES, J. C., Bordet, T., Haase, G., Castelnau-Ptakhine, L., Rouhani, S., Gilgenkrantz, H., and Kahn, A. (2002). In vivo electrotransfer of the cardiotrophin-1 gene into skeletal muscle slows down progression of motor neuron degeneration in pmn mice. Hum. Mol. Genet. 11, 1615-1625.	
	38	MANDERS, P. and Thomas, R. (2000). Immunology of DNA vaccines: CpG motifs and antigen presentation. Inflamm. Res. 49, 199-205.	
	39	MAYO, K. E., Cerelli, G. M., Rosenfeld, M. G., and Evans, R. M. (1985). Characterization of cDNA and genomic clones encoding the precursor to rat hypothalamic growth hormone-releasing factor. Nature 314, 464-467.	
	40	MCCLUSKIE, M. J., Weeratna, R. D., and Davis, H. L. (2000). The role of CpG in DNA vaccines. Springer Semin. Immunopathol. 22, 125-132.	
	41	MCRORY, J. E., Parker, R. L., and Sherwood, N. M. (1997). Expression and alternative processing of a chicken gene encoding both growth hormone-releasing hormone and pituitary adenylate cyclase-activating polypeptide. DNA Cell Biol. 16, 95-102.	
	42	MELMED, S. (1991). Extrapituitary Acromegaly. [Review]. Endocrinology & Metabolism Clinics of North America 20, 507-518.	
DS	43	MULLIGAN, K., Tal, V. W., and Schambelan, M. (1999). Use of growth hormone and other anabolic agents in AIDS wasting. JPEN J. Parenter. Enteral Nutr. 23, S202-S209.	

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DS 1	44	NARUM, D. L., Kumar, S., Rogers, W. O., Fuhrmann, S. R., Liang, H., Oakley, M., Taye, A., Sim, B. K., and Hoffman, S. L. (2001). Codon optimization of gene fragments encoding Plasmodium falciparum merozoite proteins enhances DNA vaccine protein expression and immunogenicity in mice. Infect. Immun. 69, 7250-7253.	
✓	45	SCHEULE, R. K. (2000). The role of CpG motifs in immunostimulation and gene therapy. Adv. Drug Deliv. Rev. 44, 119-134.	
✓	46	SHI, H., Yan, P. S., Chen, C. M., Rahmatpanah, F., Lofton-Day, C., Caldwell, C. W., and Huang, T. H. (2002). Expressed CpG island sequence tag microarray for dual screening of DNA hypermethylation and gene silencing in cancer cells. Cancer Res. 62, 3214-3220.	
✓	47	SHIRAISHI, M., Sekiguchi, A., Terry, M. J., Oates, A. J., Miyamoto, Y., Chuu, Y. H., Munakata, M., and Sekiya, T. (2002). A comprehensive catalog of CpG islands methylated in human lung adenocarcinomas for the identification of tumor suppressor genes. Oncogene 21, 3804-3813.	
✓	48	SOUBRIER, F., Cameron, B., Manse, B., Somarriba, S., Dubertret, C., Jaslin, G., Jung, G., Caer, C. L., Dang, D., Mouvault, J. M., Sherman, D., Mayaux, J. F., and Crouzet, J. (1999). pCOR: a new design of plasmid vectors for nonviral gene therapy. Gene Ther. 6, 1482-1488.	
DS ✓	49	WOLFF, J. A., Ludtke, J. J., Acsadi, G., Williams, P., and Jani, A. (1992). Long-term persistence of plasmid DNA and foreign gene expression in mouse muscle. Human Molecular Genetics 1, 363-369.	

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